

# Exhibit B

# GYNECARE TVT\*

## *Obturator System*

**Tension-free Support for Incontinence**

GYNECARE TVT\* *obturatorstysteem*  
Spanningsvrij steunbandje tegen incontinentie

GYNECARE TVT\* *obturatorssystem*  
Spændingsfri støtte til inkontinens

GYNECARE TVT\* *-obturaattorijärjestelmä*  
Jännityksetön tuki inkontinenssin hoitoon

*Système obturateur* GYNECARE TVT\*  
Dispositif sans tension contre les incontinences

GYNECARE TVT\* *Obturator System*  
Spannungsfreie Unterstützung bei Inkontinenz

*Sistema otturatorio* GYNECARE TVT\*  
Dispositivo tension-free per l'incontinenza

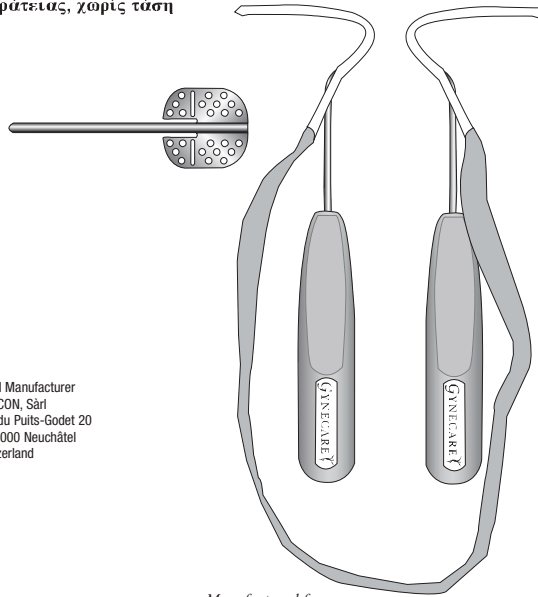
*Sistema obturador* GYNECARE TVT\*  
Apoio sem tensão para incontinência

*Sistema obturador* GYNECARE TVT\*  
Protector sin tensión para la incontinencia

GYNECARE TVT\* *obturatoribandsystem*  
Tensionsfritt stöd för behandling av inkontinens

*Σύστημα επιπωματικού* GYNECARE TVT\*  
*Σύστημα υποστήριξης για την αντιμετώπιση της*  
*ακράτειας, χωρίς τάση*

EC  
Legal Manufacturer  
ETHICON, Sàrl  
Rue du Puits-Godet 20  
CH-2000 Neuchâtel  
Switzerland



Manufactured for:

**GYNECARE**  
WORLDWIDE  
A division of **ETHICON, INC.**  
a Johnson & Johnson company  
Somerville, New Jersey 08876-0151

Made in Switzerland  
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RMC P18070/A

**ETH.MESH.02340829**

**ENGLISH****GYNECARE TVT\* *Obturator System*  
Tension-free Support for Incontinence****GYNECARE TVT *Obturator Device*,  
Sterile Single Use****GYNECARE TVT *Obturator Helical Passers*,  
Sterile Single Use****GYNECARE TVT *Obturator Atraumatic Winged Guide*,  
Sterile Single Use****Please read all information carefully.**

Failure to properly follow instructions may result in improper functioning of the device and may lead to injury.

**Important:**

This package insert is designed to provide instructions for use of the GYNECARE TVT\* *Obturator System*, including the GYNECARE TVT *Obturator device*, Helical Passers and Atraumatic Winged Guide. It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence). The device should be used only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the GYNECARE TVT *Obturator device*. These instructions are intended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

**DESCRIPTION**

The GYNECARE TVT *Obturator System* is a sterile, single patient use procedure kit consisting of:

**GYNECARE TVT *Obturator device***

The GYNECARE TVT *Obturator device* is a sterile, single patient use device, consisting of one piece of undyed or blue (Phthalocyanine blue, Color index Number 74160) PROLENE\* polypropylene mesh (tape) approximately 1/2 x 18 inches (1.1 x 45 cm) covered by a plastic sheath overlapping in the middle. Plastic tube receptacles are attached at each end. PROLENE polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE polypropylene non-absorbable surgical suture. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE mesh is knitted by a process that interlinks each fiber junction and that providing elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.

**GYNECARE TVT *Helical Passers***

The GYNECARE TVT Helical Passers are two stainless steel, curved wire passers with plastic handles that are designed to deliver the GYNECARE TVT *Obturator device*. Helical Passers are provided as left and right units, pre-assembled to the GYNECARE TVT *Obturator device*. The Helical Passer MUST not be bent or deformed in any way.

**GYNECARE TVT *Atraumatic Winged Guide***

The GYNECARE TVT Atraumatic Winged Guide is a stainless steel accessory instrument, which facilitates the passage of the GYNECARE TVT Helical Passers through the dissection tract.

**INDICATIONS**

The GYNECARE TVT *Obturator device* is intended to be used in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

**INSTRUCTIONS FOR USE**

(Note: hand positions shown in illustrations may vary)

1. Place the patient in the dorsal lithotomy position with the hips hyperflexed over the abdomen. The buttocks should be positioned flush with the edge of the table.
2. The procedure can be carried out under local, regional or general anesthesia.
3. Optionally, the labia may be sutured laterally to provide exposure.
4. Insert a urethral catheter into the bladder and empty the bladder.
5. Mark the exit points of the plastic tubes by tracing a horizontal line at the level of the urethral meatus, and a second line parallel and 2 cm above the first line. Locate the exit points on this line, 2 cm lateral to the folds of the thigh (the skin may be flattened by stretching). Mark the exit points, alternatively a 5–10 mm incision may be made at each exit point or at a later stage of the procedure. (See Figure 1)

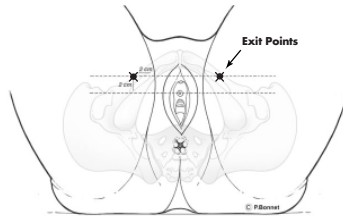


FIG. 1

6. Using Allis clamps for traction, make a 1 cm midline incision in the vaginal mucosa starting 1 cm proximal to the urethral meatus.

**(Note: It is suggested that the device insertion be completed on one side before beginning dissection of the second side.)**

Using a "push-spread technique", begin blunt dissection preferably using pointed, curved scissors. The path of the lateral dissection should be oriented at a 45° angle from the midline, with the scissors oriented either on the horizontal plane or with the tips pointed slightly upward (See Figure 2). Continue dissection toward the "junction" between the body of the pubic bone and the inferior pubic ramus. (See Figure 2)

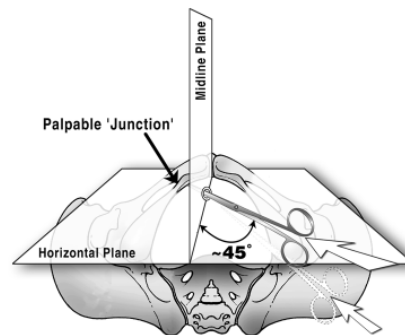


FIG. 2

When the "junction" between the body of the pubic bone and the inferior pubic ramus is reached, perforate the obturator membrane. A loss of resistance can be felt when the membrane is perforated. The channel should be approximately 5–7 mm in diameter and no deeper than 5 cm. Dissection beyond 5 cm may allow unintended entry into the Space of Retzius. If the bone is not reached after dissecting 5 cm, re-evaluate that the angle of dissection is correct.

7. Remove the GYNECARE TVT Winged Guide from the package. (See Figure 3)

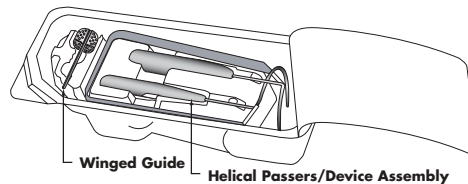


FIG. 3

8. Insert the GYNECARE TVT Winged Guide into the dissected tract until it passes the inferior pubic ramus and enters the opening previously made in the obturator membrane. Loss of resistance can be felt as the Winged Guide passes through the obturator membrane.

If difficulty is encountered during insertion of the guide, reconfirm the direction of the tract with the scissors.

**(Note: The open side of the guide must be facing the surgeon. The bendable tab can be bent to increase the length of the guide if needed, See Figure 5.)**

9. Remove the GYNECARE TVT Helical Passers/Device Assembly and the GYNECARE TVT Obturator device assembly from the sterile pack (See Figure 3 for components).

*(Note: To ensure correct orientation of the Helical Passers and tape, verify that the GYNECARE logo and thumb indent on the plastic handle are facing the surgeon, and that the points are on the outside facing the surgeon. The Helical Passer in the surgeon's left hand must be used on the patient's right side; See Figure 4.)*

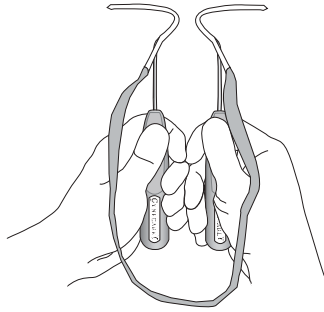


FIG. 4

10. Place one of the Helical Passers on the sterile drape or other suitable sterile location until needed. Assure that the tape is not twisted.
11. Insert the correct GYNECARE TVT Helical Passer into the dissected tract following the channel of the GYNECARE TVT Winged Guide. Push the device inward, traversing, and slightly passing the obturator membrane. Make sure the device handle is oriented so the straight tip of the Helical Passer is aligned with the channel in the GYNECARE TVT Winged Guide and remains in that orientation until the tip traverses the obturator membrane. (See Figure 5)

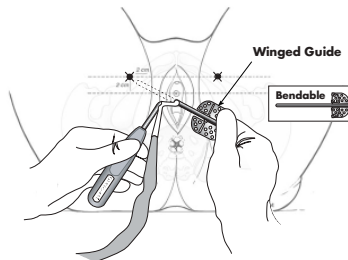


FIG. 5

12. Once in this position, remove the GYNECARE TVT Winged Guide and keep sterile for later use on the same patient.

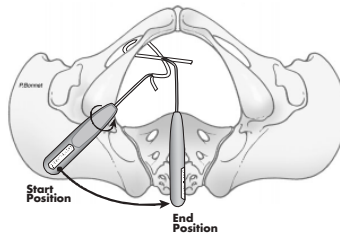


FIG. 6

13. Once the GYNECARE TVT Winged Guide has been removed, rotate the handle of the Helical Passer simultaneously as you move the handle towards the midline. (See Figure 6) **(Note: Never allow the handle to be orientated in a horizontal position.)**

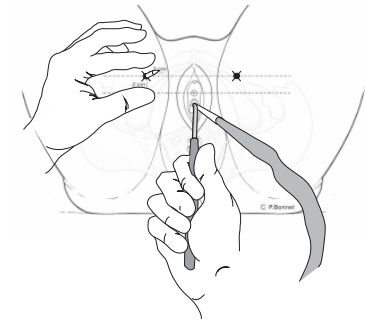


FIG. 7

14. The point of the Helical Passer should exit near the previously determined exit points (See Figure 7). However, slight skin manipulation may be required. If the skin incision has not been previously made, make it at the point where the tip of the helical passer tents the skin. When the tip of the plastic tube appears at the skin opening, grasp it with a clamp and, while stabilizing the tube near the urethra remove the Helical Passer by a reverse rotation of the handle. (See Figure 8)

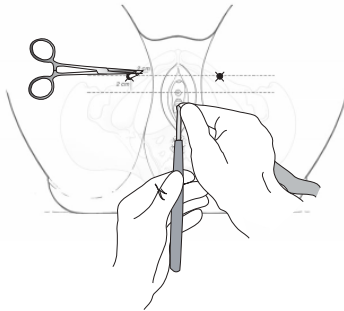


FIG. 8

15. Pull the plastic tube completely through the skin until the tape appears. (See Figure 9)

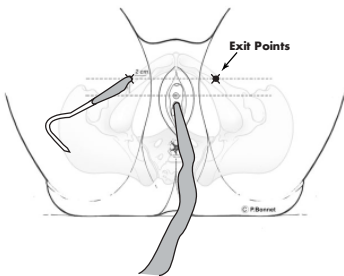


FIG. 9

16. Repeat the technique on the patient's other side ensuring that the tape lies flat under the urethra. (See Figure 10)

**(Note: If a twist in the tape is discovered, ensure that the twist is not positioned under the urethra after the excess tape is pulled through.)**

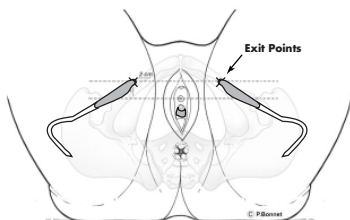


FIG. 10

17. When both plastic tubes have been extracted through the skin incisions, cut the plastic tubes from the tape and plastic sheaths. Position the tape loosely e.g. without tension, and flat under the mid-urethra. At this stage a cough test can be performed. This allows adjustment of the tape so that only a few drops of urine are lost during the cough. (See Figure 11)

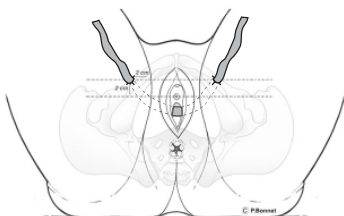


FIG. 11

When the tape is in position, remove the plastic sheath that covers the tapes. To avoid positioning the tape with tension, place a blunt instrument (e.g., scissors or forceps) between the urethra and the tape during removal of the plastic sheaths.

*(Note: Premature removal of the sheath may make subsequent adjustments difficult.)*

18. Following tape adjustment close the vaginal incision. Cut the tape ends at the exit points just below the skin of the inner thigh. Close the skin incisions with suture or surgical skin adhesive.
19. Cystoscopy can be performed at the discretion of the surgeon. If cystoscopy was performed following the first passage, make sure the bladder is emptied prior to initiating passage of the second side. Post-operative indwelling catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2–3 hours after the operation.

#### CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

#### WARNINGS AND PRECAUTIONS

- Do not use GYNECARE TVT *Obturator* procedure for patients who are on anti-coagulation therapy.
- Do not use GYNECARE TVT *Obturator* procedure for patients who have a urinary tract infection.
- Users should be familiar with surgical technique for urethral suspensions and should be adequately trained in the GYNECARE TVT *Obturator* procedure before employing the GYNECARE TVT *Obturator* device.
- Acceptable surgical practice should be followed for the GYNECARE TVT *Obturator* procedure as well as for the management of contaminated or infected wounds.
- The GYNECARE TVT *Obturator* procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to patient anatomy and correct passage of the device will minimize risks.
- Bleeding may occur post-operatively. Observe for any symptoms or signs before releasing the patient from hospital.
- Although bladder injury is unlikely to occur with this technique, cystoscopy may be performed at the discretion of the surgeon.
- Do not remove the plastic sheaths until the tape has been properly positioned.
- Ensure that the tape is placed with no tension under the mid-urethra.
- Do not perform this procedure if you think the surgical site may be infected or contaminated.

- Since no clinical information is available about pregnancy following sub-urethral sling procedure with the GYNECARE TVT *Obturator* System, the patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Since no clinical information is available about vaginal delivery following a sub-urethral sling procedure with the GYNECARE TVT *Obturator* System, in case of pregnancy delivery via cesarean section should be considered.
- Post-operatively, the patient should be advised to refrain from heavy lifting and/or exercise (e.g., cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can usually return to other normal activity after one or two weeks.
- The patient should be instructed to contact the surgeon immediately if dysuria, bleeding or other problems occur.
- Transient leg pain lasting 24–48 hours may occur and can usually be managed with mild analgesics.
- As with other incontinence procedures, de novo detrusor instability may occur following a sub-urethral sling procedure utilizing the GYNECARE TVT *Obturator* System. To minimize this risk, make sure to place the tape as described above.
- Do not contact the PROLENE mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.
- Do not resterilize GYNECARE TVT *Obturator* device or its components. Discard opened, unused devices.
- Prophylactic antibiotics can be administered according to the surgeon's usual practice.

#### ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheaths initially covering the PROLENE mesh are designed to minimize the risk of contamination.
- Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

#### ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue, that can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

#### HOW SUPPLIED

The GYNECARE TVT *Obturator* System is provided sterile (ethylene oxide) for single use. Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused devices.

#### STORAGE

Recommended storage conditions for the GYNECARE TVT *Obturator* System single use device are below 25°C, away from moisture and direct heat. Do not use after expiry date.

*CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.*

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